K071234

SECTION 11

510(k) Summary
Prepared April 30, 2007

JUN 29 2007

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Sheila W. Pickering Ph.D.
Telephone: (650) 943 7187
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Submission Date: February 16, 2007

Device Name: AcuNav Diagnostic Ultrasound Catheter

Common Name: Diagnostic Ultrasound System with Accessories

Classification:
Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Ultrasonic Imaging Catheter ; 21C FR # 892.1550; Product Code DQO

A. Legally Marketed Predicate Devices
The AcuNav Ultrasound Imaging Catheter is substantially equivalent to original AcuNav Ultrasound Imaging Catheter.

B. Device Description:

- ISO 10993-1 Biocompatibility

C. Intended Use
The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The AcuNav modifications are verified and validated according to the company's design control process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Siemens Medical Solutions USA, Inc.
c/o Ms. Sheila Pickering, Ph.D.
Senior Director of Regulatory Affairs
P.O. Box 7393
1230 Shorebird Way
Mountain View, CA 94039

Re: K071234
AcuNav Diagnostic Ultrasound Catheter 8F, 10F
Regulation Number: 21 CFR 870.1200
Regulation Name: Intravascular Ultrasound Catheter
Regulatory Class: Class II (two)
Product Code: OBJ
Dated: April 30, 2007
Received: May 3, 2007

Dear Dr. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7
Intended Use of the Device

510(k) Number (if known): K071234

Device Name: AcuNav Diagnostic Ultrasound Catheter 8F, 10F

Indications For Use:

The Acuson Acunav Ultrsound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071234